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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/553,336 | 11/27/2006 | Kenji Nagakawa | 10921.363USWO | 1215 |
| 52835 7590 08/05/2009 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902 | | | | |
| EXAMINER SAKELARIS, SALLY A | | | | |
| ART UNIT 1797 | | PAPER NUMBER | | |
| MAIL DATE 08/05/2009 | | DELIVERY MODE PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,336

Applicant(s)

NAGAKAWA ET AL.

Examiner

Sally A. Sakelariss

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-10 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850/8)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 12/11/2008 and 10/14/2005

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (product claims 1-10 and 16-24) in the reply filed on 6/25/2009 is acknowledged. Applicants traverse the restriction requirement to the extent of requesting that the non-elected claims be maintained for possible reinstatement, no substantive arguments were made.

Claims 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/25/2009.

The requirement is still deemed proper and is therefore made FINAL.

Claim Interpretation

With regard to claims 1-10 and 16-24, the examiner kindly requests that the applicants recite either "first region" OR "first part" to avoid confusion when referring to the same structure on their tool.

As to the pending claims, 16-24 below, which contain intended use terms, the Examiner will interpret these claims in light of the structural elements that are disclosed and not for their intended use as stated after the term "for." The term, "for," is an intended use term. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Exparte Masham*, 2 USPQ2d 1647 (1987). The Examiner has applied references, which are capable of meeting these functions. A structure, which is capable

of providing the intended use, is considered to meet the limitation of intended use recited in a claim to a device or an apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5-10, 16, 17, 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al. (2002333420A).

With regard to claims 1 and 16, Watanabe teach an analyzing tool comprising: a reaction space in which a particular component of a sample and a reagent react with each other [0071]; and a reagent portion which is arranged in the reaction space (8) and which dissolves when the sample is supplied to the reaction space (12); wherein the reagent portion includes a first part (12) and a second part (13) facing each other and provided on a defining surface (6) defining the reaction space (8). It should be noted that the applicant's recitation of "for analyzing the particular component by colorimetry" in claim 16 will be interpreted by the office as intended use language.

With regard to claim 2, the first part (12) and second part (13) are separated from each other.

With regard to claim 3, the first part (12 – succinic acid and potassium ferricyanide) and second part (13 – enzyme surfactant layer [0070]) differ in composition.

With regard to claims 5, 6, 16, 17 and 19, the facing distance between (9) and (1) is 0.1mm which is 100 μ m which is therefore not greater than 300 μ m, 150 μ m, or 100 μ m and not smaller than 30 μ m (Example 2 [0068]).

With regard to claims 7 and 22, the analyzing tool of claim 5 and 16 is further comprised by a first plate (1) and a second plate (9) both defining the reaction space and including respectively the first and second parts/regions (12 and 13).

With regard to claims 8 and 23, the above structure includes a spacer (7) which defines the reaction space (8) creating the facing distance.

With regard to claims 9, 10, 20, 21, and 24 blood is used as a sample which is moved through the microchannel by way of capillary action ([0083-84]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (2002333420A).

With regard to claim 18, as can be seen above, Watanabe teaches that the facing distance between (9) and (1) is 0.1 mm which is 100 μ m which is therefore not greater than 300 μ m, 150 μ m, or 100 μ m and not smaller than 30 μ m (Example 2 [0068]).

Watanabe does not teach that the facing distance is no greater than 75 μ m.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have decreased the size of the facing distance by 25 μ m for the expected benefit of controlling the capillary flow of the sample through the channel and increasing the contact with the reagents below and above the sample and furthermore since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (2002333420A) in view of Mochida et al. (US 5147607).

The teachings of Watanabe can be viewed above.

Watanabe do not teach a color developing reagent included on the reagent portion.

Mochida et al. teach a microfluidic chip wherein Figure 17a a reagent immobilization zone (30) contain reagents for the color development of a test sample (Col. 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the chromogenic reagent of Mochida in the device of Watanabe as

such a detection method provides a quick and easily interpreted result to increase the efficiency of the analysis tool (Col.2 lines 59-63).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 5712726297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sally A Sakelaris/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797